TITLE OF INVENTION

RENEW COMPRESSION SCREW

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"The Renew Compression Screw", a basic bone implant for external fixator, of an improved and renewable stability; and a lag screw with renewable compression on better mechanical principles, resulting in a durable biomechanical condition for bone union..

CROSS-REFERENCE TO RELATED APPLICATIONS

"Not applicable"

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

"Not Applicable"

REFERENCE TO A MICROFICHE APPENDIX

"Not Applicable"

BACKGROUND OF THE INVENTION

This relates to the field of Orthopaedics and Trauma, human or veterinary. It can be used for other biological fixations/immobilizations such as botanical or other forms of life and for tissues other than bone. It can be used in any engineering or mechanical endeavour in which it serves to hold and/or compress together fragments or masses of material together, while taking part in an outside construct.

Bone is living tissue. Bone fragments and surfaces can unite by biological activity over a length of time, given proper conditions to favor it. During this biological process of healing, the fragments have to be held together continuously by various means, to achieve a finally acceptable result for restoring function to the part.

The biological process is favoured by the following measures.

1. Immobilization of the fragments or surfaces attempting union.
2. Compression of the surfaces to increase the rigidity of immobilization, and also promoting the biological process of direct union without excessive callus formation.
3. Relieving recurrent stress and injury to the soft tissues and neuro-circulatory

mechanisms by immobilization.

4. Immobilizing only the healing parts, and to encourage movement and activity of un-injured parts.

This has been attempted by the following methods.

A. Continuous traction

B. External casts of Plaster of Paris, other casting materials and bracing.

C. Internal fixation.

D. External fixation.

E. Combined methods of fixation.

A. Continuous traction:

This can restore the length of the limb, and further measures can correct rotation and angulation to some extent.

The following problems of this method seldom make it the preferred treatment.

1. It is difficult to maintain the traction force continuously even with very frequent attention.

2. Patient cooperation is difficult to achieve.

3. Due to intermittent loss of traction force, malunion may occur. Distraction and movement of fragments may cause delay or failure of union.

4.Circulatory problems can occur in the distal limb.

5. Wounds in the traction surface will not allow such treatment.

B. External casts of Plaster of Paris, other casting materials and braces.

The following problems are associated with them.

1. The immobilization is not rigid enough, when this is critically essential.

2. Encircling of the part causes sweating and discomfort in hot climates.

3. Pressure sores can occur at pressure points, or due to insertion of hard objects by patient for scratching. Bugs can get in.

4. Swelling of part within the cast can cause tightness and loss of circulation.

5. Loosening of cast occurs due to loss of swelling of part, or due to moisture reducing the thickness of the padding, resulting in loss of reduction.

6. There is no access to any wounds inside, which may need regular attention, except by cutting out windows or leaving the cast incomplete, which may jeopardize the immobilization, and fracture position.

7. Uninvolved parts also are immobilized, a setback to recovery.

Due to these factors it can suffice only when rigid immobilization is not critically important, and usually in the absence of complicating factors of wounds and circulation.

C. Internal fixation:

This may be applied along the side of a bone in the form of a plate and screws of the preferred design. It allows accurate reduction when this is most desirable; a bone graft can be added and lag screws driven as often as feasible, for inter-fragmentary compression. Sliding devices can be added to passively close any gaps arising later. Disadvantages are as under:

a. Large exposures are required with relatively greater damage to the soft tissues and bone circulation. Meticulous technique may minimise this, yet the exposure is larger.

b. Compression once applied at operation wears off within hours depending on the quality of bone. There is no possibility of renewing this compression once the wound is closed over the device. It is not acceptable to re-anaesthetise and re-expose the device repeatedly to re-tighten the screws.

c. Newer minimally invasive methods are performed through smaller incisions but in order to place the plate directly on bone, the periosteum and muscle have to be stripped blindly. The plate is always unavoidably placed over some soft tissues, which melt away under the pressure and loosen the plate. Loss of torque of screws is unfavourable to biology of bone healing.

d. Plates are seldom favoured in compound fractures.

e. Fracture haematoma gets dispersed.

Internal fixation may be applied inside the medullary canal of bone in the form of nails, pins and wires.

In closed nailing, the fracture haematoma is preserved.

The disadvantages are as under.

1. It is generally not applicable to children, due to growth plates at the ends of bones.

2. It invades and occupies the bone from end to end, with the possibility of spreading infection.

3. It is not stable to rotational forces, and interlocking methods are not available for all situations.

4. In open nailing, the fracture haematoma is dispersed.

D. External fixation:

This is most ideally suited for open injuries of bone. The commonly used basic bone implant for the external fixator is the Schanz screw which can be inserted at a safe distance from the open wounds and fracture ends.

1. Access to wounds for frequent attention is easy.
2. There is no aggravation of injury to bone or soft tissue.
3. Safe corridor entries of screws prevent injury to neuro-vascular structures.
4. In transverse fracture patterns, some compression can be applied along the axis of the bone.

The following limitations remain:

1. The basic implant e.g. the Schanz screw has a tendency to loosen in bone, leading to instability and a proneness to infection. Radial preloading of the implant in bone improves the stability, by the technique of inserting a larger diameter screw in a suitably smaller drill hole, but the rod/bone interface is small.
2. The preload is only in one mode, viz. Radial
3. After loosening, there is no way of regaining any degree of stability in the same position, before the onset of infection. If the loose screw had been initially placed in the ideal site, then any next site for repositioning will be less than ideal.
4. There is no lag screw effect of a Schanz screw, to exert inter fragmentary compression. Inter-fragmentary compression greatly enhances the stability, as well as the biological process of union. Fragments can at most be splinted across, but not drawn together and compressed as in the lag screw mode, by the

conventional Schanz screw.

E. Combined methods of fixation:

When any one method is inadequate to neutralize all the forces of muscular pull and gravity, another method is added onto the first. For example, in "mini-external fixation" methods; one or two lag screws used to hold together some fragments are supplemented by an external fixator construct, or by traction.

Even with such a supplementation, the lag screws can fail, because by the blind stab-hole technique of insertion, there is always some interposition of soft tissue between the screw head and the bone surface. This soft tissue quickly undergoes pressure necrosis to loosen the compression by loss of torque. The only residual control is the external fixator, which may not be adequate for joint fragments. The compression once lost cannot be regained.

SUMMARY OF THE INVENTION:

The invention is aimed at preserving and augmenting the functions of the primary bone implant of the external fixator in which, Axial and Surface preloads are added to the older method of Radial preloading of the implant in bone. This has added effect on the stability and durability of the implant. The former two preloads are also renewable, because the screw can again be tightened after the first insertion. The triple preload widely distributes stresses from the limited rod/bone interface, which is the site of loosening of a conventional implant.

Another embodiment is a lag screw with insertion capability at a mechanically sound right angle to fracture planes, with renewable compression on loosening. Renewed and prolonged inter-fragmentary compression by external fixator is a new advantage to the

biology of bone healing.

This implant can be used to supplement minimally invasive plate osteosynthesis with double advantage. The screw torque can be renewed to keep plate firmly on bone and the same implant can form an outside construct to augment stability of implanted plate.

All positive features of the older implant are retained; permitting wound access, minimal incisions, safe corridor insertion, soft tissue preservation, and no lengthwise invasion of medullary canal of bone. No novel disadvantages are introduced.

BRIEF DESCRIPTION OF DRAWINGS

FIG 1 is a diagrammatic front elevation of the invention with lag screw capability.

FIG 2 is a cross section of the prior art basic external fixation implant in bone, showing Radial preload.

FIG 3 is a front elevation of the preferred basic external fixation implant in bone, showing the Surface preload and Axial preload in addition to the conventional Radial preload, widely distributing stress over bone/implant interfaces.

FIG 4 is an embodiment with spherical head shown concentrically countersunk into bone surface.

FIG 5 is the coronal plane view of a prior art two-piece internal fixation device commonly used to fix a proximal femoral fracture and having a screw capable of sliding within the barrel of an angled plate.

FIG 6 is the coronal view of prior art external fixator holding the same fracture as in FIG 5, without compression.

FIG 7 is the coronal plane view of the same fracture showing the preferred lag screw

device at right angles to the fracture plane for efficient compression. Both the lag screws are connected to the two preferred basic implants below, through a construct of clamps and tubes.

FIG 8 is a five-part fracture of distal femur involving the knee joint. All fracture surfaces are compressed by improved lag screws at right angles across the fracture plane. An exception is the third from below, which is compressing three fragments across two fracture surfaces and cannot be at best angles to both fractures. Two basic implants are holding the proximal fragment, connecting the smaller distal fragments to the rest of the bone.

FIG 9 shows an enlarged view of the fifth lag screw from below, of FIG 8, with the compression at right angles to the fracture plane and the screw subtends an angle of about forty-five degrees to the bone surface.

DETAILED DESCRIPTION OF THE INVENTION

FIG 1 is one embodiment of the lag screw implant. It comprises;

1 being the tip at the first end, with guide wire 7 in the central canal. The tip shown is self tapping, but optionally a non-self tapping tip may be made available.

2 is the short threaded section at the first end, the thread not extending to the head 4.

3 being the smooth screw shaft section meant for gliding through the drill hole in the fragment near the head, allowing lag screw compression.

4 is the spherical head for engaging the surface of the fragment nearer to head. The head may be integral with the rod or may be mobile for fixation at a desired level to rod 5.

5 is the unthreaded drive shaft, which serves for driving the device in or out, also for

being secured to an external fixator construct through a clamp; as well as for subsequent turning of device to renew the torque, in case of loosening.

6 is the second end which is outside the body, with a means for gripping, shown as a milled surface in the figure. The grip can also be quick coupling or faceted by triangulation, to suit the gripping handle or chuck.

7 is the guide wire passing from any one end, through the entire rod and out at the other end. It helps to direct the device at the best angle across the fracture plane.

FIG 2 shows the cross-section 11 of a prior art Schanz screw driven into a drill hole of suitably smaller diameter in bone B. This generates a Radial preload 8 at the implant/bone interface.

FIG 3 shows the basic implant inserted in bone B.

1 is the non-self cutting tip at the first end, which requires the use of a bone tap before drive.

2 is the fully threaded section from the first end to the head, providing maximum interface with bone.

4 is the conical head with base towards the bone with a blunt serrated basal surface for making blunt limited contact on bone as at 14. The head exerts a Surface preload on bone surface and on tightening the screw, the implant is axially tensioned within the bone B. These two preloads are in addition to Radial preload 8 as in prior art. The head is integral to the rod for stability.

As shown in here, basic implants are driven at right angles to bone surface, in a single fragment, when the leading base of the head 4 makes all round even contact on bone B.

The device is not canalised, making it stronger.

The overall dimensions of the device and its parts are made to suit the size of bone, the size of fragments and the depth of bone from skin. Thus in a superficial bone like the tibia, the conical head will be squat, to contain it within the skin. In a deeper bone like the femur the cone will taper taller, for easy removal.

FIG 4 shows a spherical head 4 countersunk into the bone surface B, distributing stress evenly in the countersink on tightening.

FIG 5 is a coronal view of femur with fracture F, giving rise to two fragments B and B'. A frequently used two- piece device, a sliding hip screw, is holding the fracture reduced and compressed at the time of operation. X is the hip screw and Y is the barrel of the plate in which the screw should slide out in case of absorption of fracture surfaces. The fracture can be compressed by means of a small screw Z in the outer end of the barrel. This compression wears off in time after the skin S is closed, with no possibility of recompressing. The screw may fail to slide causing a persisting gap and non- union.

FIG 6 is the same fracture F as in Fig 5, held with prior art external fixator. The fragments are splinted over the upper two Schanz screws, but no compression can be achieved. Passive sliding also cannot occur due to participation in the rigid external construct. The lower two Schanz screws are the basic implants, which can be inserted with Radial preload. When Radial preload tapers off, it cannot be renewed. No other preloads are possible in this design. Persisting gap at fracture site may lead to delay or failure of union.

FIG 7 is the same fracture F, stabilized with an external fixator using the preferred

device. The upper two screws in lag mode achieve active compression at fracture site, which can be renewed by loosening one screw at a time at the clamp, turning it tighter, and retightening the clamp.

The lower two screws are the basic implants for completion of the construct, driven with Radial preload. The head exerts Surface preload on the bone, adding to the lateral stability of the implant. In addition, there is an Axial preload created along the length of the screw, tensioned on driving it tight. Thus, there is a wider distribution of stresses compared to the prior art screw in which all load is borne at the rod/drill hole interface. The latter two are renewable at intervals, without any fresh exposures. The preloads are also mutually protective.

FIG 8 shows a five-part fracture in the lower one third of the femur, involving the knee joint, reduced and held by a fixator using the implants of invention. The fragments are B, B', B'', B''' and B''''. The fracture planes are F, F', F'', F''', F''''; of which F'' involves the joint surface.

The lower five implants are in lag mode, the partial thread engaging only one fragment near the first end. The lag screws are at right angles to the fracture planes, except the third from below. Since this is compressing three fragments B'''', B' and B'' across two fractures F'''' and F', it is at best possible angles that the situation permits. The best angle for compressing two surfaces is a perpendicular to their interface. This requires the device to be driven at various angles to the outer bone surface, making a countersunk spherical head ideal for wide contact at all angles.

The upper two are in basic mode to control B, the upper two-thirds of the bone. They are

at right angles to the bone surface for best mechanical advantage. All implants are connected through clamps 12 to the tube 13.

All the implants have capability of renewable stability and compression, which gives quicker union. This protects against instability, mechanical and biological failure and sepsis. The lowest two screws compress the articular fragments B'' and B''' to each other and stabilize them to the rest of the bone. The screws need not all be in the same plane as shown in the figure. They may tilt into different planes and require creative interconnection to other construct components.

FIG 9 is an enlarged view of the fifth lag screw from below, in FIG 8. The lag screw is driven at near right angles to the fracture plane F, which results in its near 45-degree tilt to the bone surface. The spherical head is as concentrically countersunk into bone at the acute tilt, as in FIG 4 at perpendiculars.